

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
EASTERN DIVISION  
No. 4:18-CV-9-BO

TRUDELL MEDICAL INTERNATIONAL,) )  
Plaintiff, ) )  
v. ) )  
D R BURTON HEALTHCARE, LLC, ) )  
Defendant. ) )

ORDER

This cause comes before the Court on plaintiff's motions for summary judgment as to infringement and no invalidity and defendant's motion for summary judgment as to invalidity.

As alleged in plaintiff's second amended complaint, [DE 88], this is an action asserting infringement by defendant of plaintiff's U.S. Patent No. 9,808,588 ('588) based upon defendant's manufacture, importation, use, sale, and offer for sale of oscillating positive expiratory pressure devices in the United States. A *Markman* hearing has been conducted and the disputed terms and phrases from the patent-in-suit have been constructed. [DE 225]. A jury trial is currently scheduled to commence in this matter on Monday, November 7, 2022, at Elizabeth City, North Carolina. In light of the upcoming trial in this matter, the Court enters the following summary order on the pending motions.

DISCUSSION

A motion for summary judgment may not be granted unless there are no genuine issues of material fact for trial and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If that burden has been met, the non-moving party must then come forward and establish the specific material facts in dispute

to survive summary judgment. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986). In determining whether a genuine issue of material fact exists for trial, a trial court views the evidence and the inferences in the light most favorable to the nonmoving party. *Scott v. Harris*, 550 U.S. 372, 378 (2007). However, “[t]he mere existence of a scintilla of evidence” in support of the nonmoving party’s position is not sufficient to defeat a motion for summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986). “A dispute is genuine if a reasonable jury could return a verdict for the nonmoving party. . . . and [a] fact is material if it might affect the outcome of the suit under the governing law.” *Libertarian Party of Virginia v. Judd*, 718 F.3d 308, 313 (4th Cir. 2013) (internal quotations and citations omitted). Speculative or conclusory allegations will not suffice. *Thompson v. Potomac Elec. Power Co.*, 312 F.3d 645, 649 (4th Cir. 2002).

I. Motion for summary judgment of infringement.

Plaintiff seeks summary judgment in its favor on infringement. “A determination of infringement requires a two-step analysis. First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process.” *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1364 (Fed. Cir. 2001) (internal quotation and citation omitted). The Court has construed the relevant claims in its *Markman* order. Thus, remaining is the second step, which is a question of fact. *Id.* at 1369. Accordingly, summary judgment as to infringement may be imposed in plaintiff’s favor only where no reasonable juror could determine that defendant has not infringed plaintiff’s ’588 patent.

Although plaintiff contends that defendant’s opposition to its motion for summary judgment of infringement amounts to untimely and cursory denials which are insufficient to defeat its motion, the Court disagrees. Rather, the Court determines that there are material issues of fact



which must be resolved in order to determine whether plaintiff's '588 patent has been infringed by defendant. This motion is therefore denied.

## II. Cross-motions for summary judgment as to invalidity/no invalidity.

When deciding cross-motions for summary judgment, a court considers each motion separately and resolves all factual disputes and competing inferences in the light most favorable to the opposing party. *Rossignol v. Voorhaar*, 316 F.3d 516, 523 (4th Cir. 2003). The court must ask “whether the evidence presents a sufficient disagreement to require submission to the jury or whether it is so one-sided that one party must prevail as a matter of law.” *Anderson*, 477 U.S. at 251.

An issued patent is presumed valid. *Microsoft Corp. v. I4I Ltd. P'ship*, 564 U.S. 91, 95 (2011). A party may defend against a charge of infringement by establishing invalidity. 35 U.S.C. § 282. The burden of demonstrating the invalidity of a patent is by clear and convincing evidence. *Microsoft*, 564 U.S. at 96.

### A. Defendant's motion for summary judgment of invalidity.

Defendant argues that the '588 patent “is invalid because it does not meet the patentability requirements of written description and enablement, part of the bargain with the public in exchange for the right to exclude others during the patent term.” [DE 255]. Defendant raises three contentions in support of its motion for summary judgment: (1) that the '588 patent does not include a written description of an invention that only has a single vane, or an invention where the valve moves back and forth instead of in a circular fashion; (2) the '588 patent does not enable one of skill in the art to make or use an invention that has only a single vane, or an invention where the valve moves back and forth instead of in a circular fashion, and (3) that one cannot make a working invention described by the '588 patent using a single vane.

Disputed issues of material fact exist in this case which prevent entry of summary judgment in favor of defendant on the issue of invalidity. For example, a specification must include a sufficiently specific written description of the invention so as to enable a person skilled in that art to make and use the invention. 35 U.S.C.A. § 112(a). “Enablement is a legal question based on underlying factual determinations.” *Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 684 (Fed. Cir. 2015). Defendant contends that plaintiff’s ’588 patent does not enable a single-vane invention, but plaintiff’s expert has opined that a person of ordinary skill in the art *would* be able to make and use a single-vane device without undue experimentation. [DE 242-2 ¶¶ 424-67]. “[I]t is well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation[, and] [w]hether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Defendant has not satisfied its burden to demonstrate that summary judgment on invalidity is appropriate. The motion is denied.


B. Plaintiff’s motion for summary judgment on no invalidity.

The Court will not enter summary judgment in favor of plaintiff on invalidity at this time. Plaintiff’s arguments in support of summary judgment on this issue primarily concern defendant’s expert evidence, or lack thereof, and defendant’s late disclosure of a theory of invalidity. The Court determines, however, that sufficient issues of fact exist and that it will permit defendant to raise its invalidity defense at trial. This motion is also denied.

CONCLUSION

Accordingly, for the foregoing reasons, the motions for summary judgment [DE 240, 248, 254] are DENIED. The case will proceed to trial on Monday, November 7, 2022.

SO ORDERED, this 2 day of November 2022.

  
TERRENCE W. BOYLE  
UNITED STATES DISTRICT JUDGE